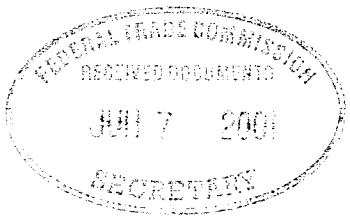
PUBLIC VERSION

In the Matter of Schering-Plough Corporation, a corporation, Upsher-Smith Laboratories, a corporation, and American Home Products Corporation, a corporation	)	Docket No. 9297

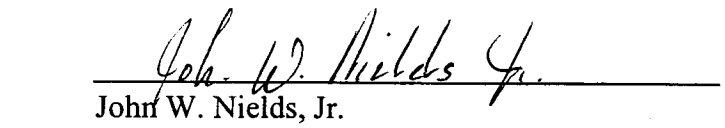


RESPONDENT SCHERING-PLOUGH CORPORATION'S MOTION FOR PARTIAL DISMISSAL OF THE COMPLAINT

Pursuant to Rule 3.22(e) of the Commission's Rules of Practice, 16 C.F.R. § 3.22(e), Schering-Plough Corporation ("Schering") respectfully moves for partial dismissal of the Complaint. The allegations of the Complaint that Schering's settlement agreements with Upsher-Smith Laboratories ("Upsher") and ESI-Lederle ("ESI") violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 ("FTC Act"), on the ground that they allegedly delayed entry of Upsher's and ESI's generic versions of Schering's K-Dur 20, are subject to dismissal because they fail to state a claim on which relief could be granted. In addition, the allegations of the Complaint that the Upsher settlement agreement violates the FTC Act, on the ground that it allegedly has the effect of blocking generics manufactured by third parties, are subject to dismissal because they fail to state a claim on which relief may be granted. For the reasons set

forth in the accompanying memorandum, Schering respectfully requests that its motion be granted.

Respectfully submitted,



John W. Nields, Jr.
Marc Schildkraut
Laura S. Shores
Chares A. Loughlin
HOWREY SIMON ARNOLD & WHITE, LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 783-0800

Attorneys for Respondent
Schering-Plough Corporation

Dated: June 7, 2001

PUBLIC VERSION

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of	)	
Schering-Plough Corporation, a corporation,	)	
Upsher-Smith Laboratories, a corporation,	)	Docket No. 9297
and	)	
American Home Products Corporation, a corporation	)	

MEMORANDUM IN SUPPORT OF RESPONDENT SCHERING-PLOUGH CORPORATION'S MOTION FOR PARTIAL DISMISSAL OF THE COMPLAINT

Pursuant to Rule 3.22(e) of the Commission's Rules of Practice, 16 C.F.R. § 3.22(e), Schering-Plough Corporation ("Schering") submits this memorandum in support of its motion for partial dismissal of the Complaint in the above-captioned case.

INTRODUCTION

This Complaint arises out of two separate settlements by Schering-Plough (Schering) of two separate patent infringement lawsuits, one against Upsher-Smith (Upsher) and one against ESI-Lederle (ESI). Schering markets a sustained release potassium product called K-Dur, and owns a patent on K-Dur's sustained release mechanism. Each lawsuit alleged that the defendant (Upsher or ESI) was planning to market a generic version of K-Dur that infringed Schering's patent, and each lawsuit sought to enjoin the marketing of the generic until the expiration of Schering's patent in 2006. The Upsher lawsuit was settled in June 1997 and the ESI lawsuit was

settled in June 1998. Under the settlement agreements, Upsher and ESI each agreed not to market their generic versions of K-Dur for *part of* the remaining life of the patent: until 2001 in the case of Upsher, and until 2004 in the case of ESI. And under the settlements, Schering agreed to permit Upsher and ESI to market their generic products after those dates. The agreements had the effect of bringing generic versions of K-Dur to the market five years before the patent expired (in the case of Upsher) and two years before the patent expired (in the case of ESI).

The Complaint alleges that these settlement agreements violate Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, in two respects relevant to this motion. The Complaint claims (A) that the agreements are unlawful because they delay the entry of the Upsher and ESI generic versions of K-Dur. Complaint ¶¶ 44, 55. The Complaint claims (B) that the Upsher agreement is unlawful because it allegedly has the effect of blocking other generics from entering the market. For the reasons set forth herein, each of these claims is deficient, and dismissal of these aspects of the Complaint is therefore warranted.[1]

A. The Alleged Agreements Not to Compete

The Complaint alleges that the settlement agreements are anticompetitive principally because of the provisions under which Upsher and ESI agreed not to market their products for part of the remaining life of Schering's patent. Complaint ¶¶ 44 and 55. But the Complaint fails to make any allegation that would, in light of the legal monopoly conferred by Schering's patent, render these provisions of the settlement agreements illegal. A valid patent gives its holder the

---

[1] We do not address, at this time, the tertiary allegation in the Complaint—that the language in the settlement agreements prevent Upsher and ESI from marketing not only the products at issue in the patent lawsuits, but also clearly non-infringing products. Complaint ¶¶ 44 and 55. This tertiary allegation is wrong for at least two reasons which may require factual development and thus are not yet ripe for dismissal. First, the agreements were demonstrably intended only to prevent Upsher and ESI from marketing products presenting substantially the same infringement issues as the products at issue in the patent suit being settled. Second, neither Upsher or ESI had the ability or intent to make any product competing with K-Dur, other than the generics at issue in the suits.

legal right to exclude from the market competitors whose products infringe the patent. And the Complaint contains no allegation either that Schering's patent was invalid or that Upsher and ESI's products did not infringe it. Without such allegations, the Complaint merely alleges that Schering did something it has an absolute right to do under its patent.

Further, the parties to any litigation have a right to resolve that litigation by settlement, with the plaintiff accepting less than all the relief sought in the lawsuit. And, parties may settle a *bona fide* patent dispute so long as the settlement "[is] not more anticompetitive than a likely outcome of [the] litigation." 12 Herbert Hovenkamp, *Antitrust Law* ¶ 2046 at 265-66 (1999). But the Complaint fails to allege that the patent disputes at issue here were other than *bona fide*, and the Complaint fails to allege that the settlements are more anticompetitive than the likely outcome of the litigation.

The settlement agreements at issue in this Complaint concededly arose out of *bona fide* patent disputes. The Complaint fails to allege that the patent was invalid or not infringed. And the Complaint fails to allege that the settlement agreements were more anticompetitive than the likely outcome of the litigation. Consequently, the Complaint fails to state a claim and must be dismissed.

B. The Alleged Agreements to Keep Third Party Generics Off the Market

The Complaint alleges that the Upsher settlement is anticompetitive secondarily because it has the effect of excluding from the market non-infringing generics which might be made by third parties. The Complaint does not allege that the settlement agreement's own terms provide for such a result. Instead, the Complaint alleges that, *by operation of federal FDA law*, Upsher (as the first generic filer) is entitled to 180 days of exclusivity for its generic; and that third parties are prevented by law from marketing generic versions of K-Dur until 180 days after Upsher is permitted to market its product under the settlement agreement. Complaint ¶¶ 2, 29, 47, 50, & 66.

As a matter of settled antitrust law, these allegations provide no basis on which to declare the settlement agreements illegal. As a threshold matter, the Complaint does not accurately describe FDA law. It is not clear that Congress intended for a first generic filer to be able to settle a patent suit, agree to stay off the market for a period of years, and still block all other generics in the interim. Indeed, under the FDA regulations in effect at the time of the Upsher settlement, Upsher, by settling, *lost* all of its rights to block third party generics. Currently, the FDA law on this point is unresolved. *See infra* at 10-15.

But if, as the Complaint alleges, Congress did intend to extend marketing exclusivity to a settling party like Upsher, that would not make the Schering-Upsher settlement agreement unlawful. Under settled antitrust doctrine, private parties cannot be held liable for anticompetitive consequences which result from actions and decisions of the federal government. "[W]here a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, no violation of the Act can be made out." *E. R. Presidents Conference v. Noerr Motors Freight, Inc.*, 365 U.S. 127, 136 (1961).

This case is different from the Hoechst/Andrx case. There, the parties expressly provided by private agreement that the generic company (Andrx) would not transfer its exclusivity rights. Here, there was no agreement at all regarding the generic manufacturer's exclusivity rights. To the extent that Upsher has the ability to block third parties during the time it has agreed to stay off the market, that ability is completely a product of federal government decision. Consequently, the allegations in the Complaint that the settlement agreement is illegal because third party generics are blocked from the market by operation of law should be dismissed.[2]

---

[2] Of course, Schering disputes many of the other essential allegations of the Complaint, most particularly the claims that the licensing transactions entered into at the time of the settlements were the product of other than arm's length, *bona fide* negotiations for fair value.

ARGUMENT

POINT I

THE ALLEGED AGREEMENTS THAT UPSHER AND ESI WOULD NOT MARKET THEIR GENERIC VERSIONS OF K-DUR FOR *PART OF* THE REMAINING LIFE OF THE PATENT

In sections headed "Schering/Upsher Agreement Not To Compete" and "Schering/ESI/AHP Agreement Not To Compete," the Complaint alleges that each settlement agreement provides that Upsher or ESI will not market its competing generic version of K-Dur for part of the life of Schering's patent. Complaint ¶¶ 38-50, ¶¶ 51-60. The agreements not to market for part of the patent life are the principal restraints challenged in the Complaint. Under some circumstances, an allegation that one company has agreed not to market a product that competes with a product marketed by another company would be sufficient to state a claim. But in light of Schering's unquestioned right to exclude those who infringe its patent, the existence of which is central to this case, such an allegation – without more – is woefully inadequate.

A. The Complaint Fails to Allege Patent Invalidity or Non-Infringement

The Complaint expressly recognizes that Schering holds "a formulation patent ... Patent No. 4,863,743 (the "'743 patent"), which claims a controlled release potassium chloride tablet." Complaint ¶ 34. The '743 patent does not expire until September 5, 2006. *Id.* By law, the patent gives Schering an absolute right until September 2006 to exclude competitors who seek to market a product covered by its patent. The patent confers upon Schering the legal right to restrain competition from infringing products until 2006.

This right to exclude is "the essence" of the patent grant. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). It gives Schering the absolute legal right to license its patented product to some and not others, or not to license at all. *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918) ("[A patent's] strength is in the restraint, the right to exclude

others from the use of the invention, absolutely or on the terms the patentee chooses to impose"); *Ethyl Gasoline Corp. v. United States*, 309 U.S. 436, 457 (1940). The Chair of the Commission at the time this Complaint was filed has stated "I have no quarrel with the fundamental rule that a patent holder has no obligation to license or sell in the first instance. A patent holder is not under any general obligation to create competition against itself within the scope of its patent." *See* Robert Pitofsky, *Challenges of the New Economy: Issues at the Intersection of Antitrust and Intellectual Property*, 68 Antitrust L.J. 913, 922 (2001).

This right is granted by Congress under a federal statute, 35 U.S.C. §§ 154, 271(a) (1994), and therefore is necessarily recognized by the antitrust laws. As explained by the United States Supreme Court, "[t]he patent laws, which give a 17-year monopoly on 'making, using, or selling the invention' are in pari materia with the antitrust laws and modify them pro tanto." *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964). *See also United Shoe*, 247 U.S. at 57 (the "exertion [of the right to exclude in the] field covered by the patent law is not an offense against the Anti-Trust Act."). Thus, in keeping with this clear and long-settled Supreme Court precedent, courts routinely hold that a patent owner cannot be held liable under the antitrust laws for enforcing its patent or refusing to license its patent to others.[3]

---

[3] 35 U.S.C. § 271(d)(4)(1994). *See also Miller Insituform, Inc. v. Insituform of N. Am. Inc.*, 830 F.2d 606, 609 (6th Cir. 1987) (a patent holder "cannot be held liable under Section 2 . . . by refusing to license the patent to others"); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1204 (2d Cir. 1981) ("a patent holder['s] . . . 'right to exclude . . .' by refusing unilaterally to license his patent . . . is expressly permitted by the patent laws . . . .") (citation omitted); *Servicetrends v. Siemens Med. Sys.*, 870 F. Supp. 1042, 1056 (N.D. Ga. 1994) ('No court has ever held that the antitrust laws require a patent holder to forfeit the exclusionary power inherent in his patent the instant his patent monopoly affords him monopoly power over a relevant product market.') (citation omitted); *United States v. Westinghouse Elec. Corp.*, 648 F.2d 642, 647 (9th Cir. 1981) ("[T]he right to invoke the State's power to prevent others from utilizing [the patent holder's] discovery without his consent" is the essence of the patentee's statutory monopoly. The right to license that patent, exclusively or otherwise, or to refuse to license at all, is the "untrammeled right" of the patentee") (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969)) (internal quotations omitted).

The Complaint completely ignores this fundamental principle. The Complaint alleges that the settlements prevented Upsher and ESI from entering the market as competitors, but does not contest the validity of Schering's patent. Nor does it claim that Upsher's and ESI's proposed products do not infringe the patent. If Schering's patent is valid and infringed by the proposed Upsher and ESI products, however, Schering has a *legal right* to exclude those proposed products from the market until September 2006, when Schering's patent expires. Without an allegation that Schering's patent is invalid or is not infringed, plaintiff's Complaint merely alleges that Schering did something that it has an absolute legal right to do. The Complaint therefore must be partially dismissed.

B. The Complaint Fails to Allege the Patent Suit Was Not Bona Fide Or That the Settlement Was More Anticompetitive Than the Probable Outcome of the Litigation

Further, parties to a patent lawsuit have an absolute right to settle the lawsuit, with each party receiving less than if they had won. As the United States Supreme Court has explained:

> Where there are legitimately conflicting claims or threatened interferences, *a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act.* An interchange of patent rights and a division of royalties according to the value attributed by the parties to their respective patent claims is frequently necessary if technical advancement is not to be blocked by threatened litigation.

Standard Oil Co. v. United States, 283 U.S. 163, 171 (1931) (citations omitted) (emphasis added).

The leading treatise on antitrust law explains the principle this way: the settlement of a patent dispute does not unreasonably restrain competition if the settlement is a reasonable accommodation of a bona fide dispute between the parties, and "is not more anticompetitive than a likely outcome of [the] litigation." 12 Hovenkamp, *supra*, at 266. Thus, an agreement resolving patent infringement litigation cannot be held unlawful if the parties split the remaining

life of the patent in a manner consistent with the parties' objective chances of prevailing in the underlying patent suit.[4]

The Complaint fails to allege that the patent disputes between Schering and Upsher and between Schering and ESI were not *bona fide*, or that the parties' views in the lawsuits were not legitimately conflicting. And the Complaint fails to allege that the settlements were more anticompetitive than the likely outcome of the litigation. The settlements reflected the parties' objective chances of success in the underlying lawsuits, and the Complaint fails to allege otherwise. Consequently, the Complaint fails to allege anything that would make the settlements illegal.

This point is fundamental to this case. The settlement agreements cannot be, and are not, in violation of the antitrust laws unless they are more anticompetitive than the likely outcome of the litigation they settled. *See* Hovencamp, *supra*, ¶ 2046. If the settlements are not more anticompetitive than the likely outcome of the litigation, the settlements harm neither consumers nor competition. As one of the Commissioners said recently, the Commission necessarily must show that "the world that the parties created by the challenged agreement" is worse for consumers than "the 'but for' world that would have existed in the absence of an agreement." Thomas B. Leary, *Antitrust Issues in Settlement of Pharmaceutical Patent Disputes*, Prepared Remarks at the Sixth Annual Health Care Antitrust Forum (Nov. 3, 2000).

Here, the "but for" world would have been a continuation of the underlying patent litigation. But the Complaint fails to allege that the "but for" world of continued litigation would have been better for consumers than the settlements. Upsher and ESI might have lost the litigations and been barred from the market until 2006. Quite obviously, taking their chances on

---

4 Thus, for example, if Schering and Upsher split the remaining life of Schering's patent 50-50--so that Schering retained its exclusivity for half of the remaining patent period and Upsher came on the market for the second half of the remaining patent period--the settlement cannot be anticompetitive if the parties' objective chances of success in the patent case were likewise 50-50.

continued litigation may have been worse for consumers and competition than the settlements; and the Complaint does not allege otherwise. As a consequence, the Complaint fails to state facts which, if true, would constitute a violation of law, and the Complaint must be partially dismissed.[5]

POINT II

THE EFFECT THE SETTLEMENT MAY HAVE ON THE ABILITY OF THIRD PARTIES TO MARKET GENERIC VERSIONS OF K-DUR

The Complaint alleges that another anticompetitive consequence flows from the Upsher settlement. The Complaint alleges that, *by operation of federal law*, the Upsher settlement agreement blocks third parties from marketing generic versions of K-Dur until 180 days after Upsher starts selling its generic under the terms of the settlement. The Complaint also alleges that, under the same federal law, a litigated decision in the Upsher patent case would not have blocked third parties. Complaint ¶¶ 29, 47, 66. Even if these allegations correctly state the law, and it is not clear that they do, they would provide no basis upon which to declare the settlement unlawful. Under settled antitrust doctrine, private parties cannot be held liable for anticompetitive outcomes dictated by federal government action or decision.

A. The Allegations of the Complaint

The Complaint correctly alleges that Upsher was the first firm filing an abbreviated new drug application ("ANDA") for a generic version of K-Dur. And the Complaint correctly alleges that, under certain circumstances, the Hatch-Waxman Act gives the first filer for a generic version of a particular brand name drug a 180-day period of protection from competition from other generic versions of the drug. Complaint ¶¶ 13, 15, 38.

---

5 The Complaint does allege that continued litigation would have been better for consumers than the settlement in its effect on entry into the market by third party generic manufacturers. Complaint ¶¶ 47, 66. We respond to this allegation in Point II, *infra*.

The Complaint then makes a questionable allegation about how Upsher's 180-day exclusivity rights operate in the context of a settlement like the one Upsher entered into with Schering. The Complaint alleges that, under the Hatch-Waxman Act, the settlement of a patent suit against a first filer blocks entry of other generics until 180 days after the first filer starts marketing its product under the settlement. Complaint ¶¶ 29, 47, 66.

B. The Relevant FDA Law

It is not clear whether Congress intended a first ANDA filer to be able to settle a patent suit, agree to stay off the market for a term of years, and still block all other generics in the interim. The FDA regulations in effect when the Upsher case was settled did not provide for this result, and neither do the currently proposed regulations. The Complaint is thus clearly incorrect when it alleges that "*[a]t all times relevant herein*, FDA final approval of an ANDA for a generic version of K-Dur 20 for anyone other than Upsher-Smith was blocked." Complaint ¶ 29. As Complaint counsel knows very well, the regulation in existence when Schering settled with Upsher clearly provided that *by settling*, Upsher *lost* all exclusivity rights and all rights to block third party generics.[6]

The relevant law developed as follows: Under the Hatch-Waxman Act, the first ANDA filer is entitled, under certain circumstances, to a 180-day period during which no other generic may enter the market. This exclusivity right arises if the brand name product is protected by a patent, *and* if the first ANDA filer *certifies* "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is

---

6 Complaint Counsel recently asserted in a letter to counsel for one of the respondents that under the regulations in effect at the time of the Upsher settlement, Upsher "had to successfully defend a patent infringement suit before it was eligible for the 180-day exclusivity right." Letter from Karen Bokat to Michael N. Sohn, attached hereto as Exhibit 1, at 2. Complaint Counsel explained further that "because of FDA's existing 'successful defense' regulation, there was a possibility that Upsher would not be entitled to the exclusivity right until after it successfully defended its patent litigation with Schering." By settling, of course, Upsher had given up any chance that it would ever "successfully defend" the patent case.

submitted."[7] This certification is known as a "Paragraph IV certification." It is reasonable to infer from this certification requirement that Congress intended for the 180-day exclusivity period to be enjoyed only by generics that do not infringe a valid patent, although the statute nowhere says this expressly.

The statute contemplates that the brand name manufacturer holding the patent will be promptly notified of the Paragraph IV certification, signaling that the first filer believes it is legally entitled immediately to market its generic product notwithstanding the patent. If the brand name manufacturer sues the first filer for infringement within forty-five days of receiving the notice, then approval of the first filer's ANDA will be stayed for thirty months.[8] The Hatch-Waxman Act does not say expressly that the first generic filer must *win* the lawsuit to obtain exclusivity rights. The Hatch-Waxman Act does provide, however, that the 180-day exclusivity period begins to run from the earlier of (1) "the date of a decision of a court in an action ... holding the patent which is the subject of the certification to be invalid or not infringed"; or (2) the date of the generic filer's first commercial marketing of its ANDA product.[9] That is all the statute itself actually says on the subject of a first filer's 180-day exclusivity rights.

The 180-day exclusivity right of a first generic filer imposes a clear restraint on competition. It restrains other generics from entering the market until the 180-day exclusivity period is over. However, it is a restraint brought about by Act of Congress, because Congress believed the restraint would advance the public interest by encouraging the first generic to pursue its ANDA and to defend any patent infringement suit. Manifestly, this restraint on competition from other generics, which was enacted by Congress, supercedes and does not violate the antitrust laws.

---

7 21 U.S.C. § 355(j)(2)(A)(vii)(IV)(Supp. V 1999).

8 21 U.S.C. § 355(j)(5)(B)(iii)(Supp. V 1999).

9 21 U.S.C. § 355(j)(5)(B)(iv)(II)(Supp. V 1999).

The statute does not seem to have envisioned the possibility that the patent case might be settled. As the FDA said in a recent letter to a generic company:

> The statute appears to contemplate that there will be a decision on the patent status of the drug and does not identify what to do if the litigation is settled without a decision on the patent.[10]

Thus, Congress' intent on the question of the exclusivity right of a first filer who settles a patent case is not completely clear. At the time of the Upsher-Smith settlement, on June 17, 1997, there was an FDA regulation in effect that *prevented* first filers who settled from blocking other generics. That regulation did not expressly mention settlements. However, it provided that a first ANDA filer received 180 days exclusivity only if and when it "successfully defended" the patent suit.[11] Because a first filer who *settled* the patent lawsuit necessarily gave up any possibility that it would successfully defend that suit, a settling first filer lost any exclusivity rights it might have had. The Commission is fully aware of this regulation and of the fact that it was in effect in 1997, at the time of the Upsher settlement. Thus, in its Analysis to Aid Public Comment in the Hoechst/Andrx matter, the Commission stated at page 2, "At the time the Respondents entered into the challenged agreement in 1997, the governing FDA regulations required that an ANDA applicant *successfully defend* the patent holder's patent suit in order to be entitled to this exclusivity." (Emphasis added.)

A district court opinion in the District of Columbia in early 1997, in a context *other than* a settlement, stated that the successful defense requirement was invalid. *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997), *aff'd*, 140 F.3d 1060 (D.C. Cir.

---

10 Letter from Janet A. Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Deborah A. Taskot, Senior Director, Regulatory Affairs, Teva Pharmaceuticals USA, Inc., 1510 Delp Drive, Kulpsville, PA 19443, dated Feb. 6, 2001 ("Woodcock letter"), at 6.

11 21 C.F.R. § 314.107(c)(2)(1989).

1998). But the FDA was appealing that decision, and the regulation was still in place. It would have been reasonable for a party, like Schering, to assume at the time of the Upsher settlement in June 1997 that the settlement would deprive Upsher of its exclusivity rights, and open the market up to other generics if there were any that did not infringe Schering's patent.

After April 1998, the FDA withdrew the successful defense requirement from its regulations.[12] The reason was that on April 14, 1998, the Court of Appeals for the D.C. Circuit had held that the successful defense requirement was overly broad. *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998).[13] The successful defense requirement provided that the first filer could not acquire any exclusivity rights *until* it had won the patent case. The court of appeals struck it down because it deprived a first filer of exclusivity, and permitted another generic to enter the market, even when the first filer was still defending the patent suit and might still win. Calling the successful defense requirement a "win first" rule, and pointing out that the FDA could have adopted a "wait and see" approach, so that exclusivity would obtain if the first filer eventually won the patent case, the Court struck down the rule. The Court noted that "The FDA could have adopted a more narrow solution to the problem . . . ." 140 F.3d at 1069.

After the courts invalidated the FDA regulation containing the successful defense requirement, the FDA proposed a new set of regulations. These were published in the Federal Register on August 6, 1999.[14] The proposed regulations devote a section expressly to settlement agreements.[15] These proposed regulations would grant a first filer who settles the

---

12 *See Guidance for Industry on 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act* 63 Fed. Reg. 37890 (July 14, 1998).

13 The Fourth Circuit also invalidated the regulation in an unpublished opinion in April 1998. *Granutec, Inc. v. Shalala*, 46 U.S.P.Q. 2d (BNA) 1398 (1998).

14 *180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications*, 64 Fed. Reg. 42873 (Aug. 6, 1999) (proposed rule).

15 *See* section headed "D. Settlement Agreements," at 64 Fed. Reg. 42880.

patent suit a *limited* type of exclusivity. Under a settlement agreement like the Schering-Upsher agreement, the proposed regulations provide for the first filer's exclusivity rights to terminate no later than 360 days after any other generic is ready to market its product, regardless of when the first filer markets its product under the settlement.[16] Thus, these proposed regulations also do not conform to the Complaint's version of the FDA law.

These regulations have not been finally adopted. Thus, since its withdrawal of the successful defense requirement, FDA has had no applicable set of regulations. It has been "regulating from the statute."[17] During the period in which it has regulated from the statute, the FDA has written one public letter that addresses 180-day exclusivity rights in the settlement context.[18]

In that letter, dated February 6, 2001, the FDA discusses a settlement of a patent suit by Mylan, which was a first ANDA filer. The letter first observes that the "statute does not identify what to do if the litigation is settled." *Id.* at 6. The letter states, therefore, that the "FDA must determine the effect of this settlement." *Id.* After noting that the statute should be construed to avoid an "anticompetitive" result, the letter states that, having settled,

> Mylan is no longer participating in litigation intended to prove that its product will not infringe the listed patent. Moreover, despite the fact that its ANDA has been approved for more than a year, Mylan has never marketed its own ANDA product. Those facts lead FDA to presume that Mylan believes the product described in its ANDA may infringe the listed patent . . . . [19]

---

16 *See* 64 Fed. Reg. at 42880. FDA had considered proposing a regulation providing that settlements would render the first filer ineligible for any exclusivity rights. *Id.*

17 63 Fed. Reg. at 37890-91 (July 14, 1998); Woodcock letter, *supra* at 2 n.8.

18 Woodcock letter, *supra.*

19 *Id.* at 6.

Consequently, the letter concludes that Mylan's settlement undercut its Paragraph IV certification, and the FDA denied Mylan any exclusivity rights.

On April 18, 2001, a federal district court in West Virginia disagreed with FDA's view that Mylan had relinquished its exclusivity rights by settling. *Mylan Pharm., Inc. v. Thompson*, No. 1:OICV23, slip op. at 22 (N.D. W.Va. Apr. 18, 2001). It concluded that FDA's interpretation of the statute was an unreasonable one. *Id.*

The point of all the above is this: granting exclusivity rights to a settling first filer leads to a restraint on competition from other generics, as the Complaint alleges. It also has the procompetitive effect of encouraging the first filer to file its ANDA and to take on the brand name company in patent litigation. Consequently, from a public policy point of view, there are pluses and minuses to extending exclusivity rights to a first filer who settles and compromises the patent suit. The FDA and the courts have not finally declared what they believe the Hatch-Waxman Act intended in the case of settlements by first filers. But whatever decision is reached will be a *government* decision. And the Complaint cannot brand the Schering-Upsher settlement illegal because of anticompetitive consequences dictated by Act of Congress and FDA decision.

C. The Noerr-Pennington Doctrine

The United States Supreme Court has repeatedly held that "where a restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action, no violation of the Act can be made out." *Noerr*, 365 U.S. at 136. *See also United States v. Rock Royal Coop., Inc.*, 307 U.S. 533, 560 (1939) ("If the Act and Order are otherwise valid, the fact that their effect would be to give cooperatives a monopoly of the market would not violate the Sherman Act."); *cf. Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499 (1988) (when *source* of restraint is government action, no antitrust violation).

The reason for this rule was explained by the Supreme Court in *Noerr*:

> These decisions rest upon the fact that under our form of government the question whether a law of that kind [*i.e.*, one leading to a restraint on competition] should pass, or if passed be enforced, is the responsibility of the appropriate legislative or executive branch of government so long as the law itself does not violate some provision of the Constitution.

365 U.S. at 136.

It is unclear whether it was the intent of the Hatch-Waxman Act for a first filer to be able to block other generics after capitulating in a patent suit, and agreeing to stay off the market for part of the life of the brand name manufacturer's patent. If the Courts and the FDA conclude that the statute intended no exclusivity for first filers who settle, then the Complaint is wrong as a matter of FDA law: there is simply no restraint. However, if the courts and FDA conclude that the statute intended to award the first filer who challenges a patent with marketing exclusivity, even if the first filer settles the case rather than litigating it to conclusion, then Schering is not liable for the anticompetitive consequences of this governmental decision.

Professor Areeda states that any law passed by Congress "declares the public interest as perceived by the legislature" and he explains:

> To be sure, the legislature may be mistaken or unaware of the consequences of its actions, or it may be responding to political pressures not truly reflecting "the public interest," but the antitrust court may not reappraise the legislature's assessment of the public welfare. Government is ordinarily its own judge of how much competition is desirable. Further, if a statute excludes everyone but the monopolist from a market, the monopolist cannot itself be faulted. Nor is there fault for requesting or otherwise promoting the legislation. Not only is petitioning protected, but the immediate cause of the restriction on competition is the governmental action.

1 Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶ 202b, at 158 (2000)(footnotes omitted).

The possible exclusion of third party generics from the market, alleged in the Complaint, is the result of a law passed by Congress and interpreted and applied by FDA. As a matter of law, Schering may not be held liable for an anticompetitive consequence which results from actions and decisions of the federal government. The allegation that the Upsher settlement agreement is illegal because third parties are excluded from the market should be dismissed.[20]

---

[20] Finally, it should be noted that no non-infringing third party generic is ready for the market yet anyway. The Complaint makes a conclusory allegation that Schering's settlement with Upsher "has the effect of delaying entry into the relevant market by any other potential generic competitor." Complaint ¶ 66. The Complaint fails to allege, however, that any non-infringing third-party generic products have actually received FDA approval to enter, and are being kept off the market because of Upsher's alleged exclusivity. Indeed, the Complaint's only reference to a specific third party generic--Andrx Corporation--fails to allege that Andrx has received FDA approval. Complaint ¶¶ 61-62. And in fact, neither Andrx, nor any other non-infringing generic, has received such FDA approval. Without such an allegation, plaintiff cannot show that any alleged delay in the entry of non-infringing third-party generics is the result of Schering's settlement with Upsher. Rather, it appears that any alleged delay is the result of those products' failure to secure FDA approval.

CONCLUSION

For the reasons stated above, Schering-Plough Corporation respectfully requests that the Court grant its motion for partial dismissal of the Complaint.

Respectfully submitted,

John W. Nields, Jr./LSS

John W. Nields, Jr.
Marc G. Schildkraut
Laura S. Shores
Charles A. Loughlin
HOWREY SIMON ARNOLD & WHITE LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 783-0800

Attorneys for Respondent
Schering-Plough Corporation

Dated: June 7, 2001

CERTIFICATE OF SERVICE

I hereby certify that this 7th day of June, 2001, I caused an original, one paper copy and an electronic copy of the Motion of Respondent Schering-Plough Corporation For Partial Dismissal and Memorandum in Support of Respondent Schering-Plough Corporation's Motion For Partial Dismissal of the Complaint to be filed with the Secretary of the Commission, and that two paper copies and and electronic copy were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

and one paper copy was served by regular United States mail, postage prepaid, upon each of the persons listed below:

Richard A. Feinstein
Assistant Director
Bureau of Competition
Federal Trade Commission
Room 3114
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Karen Bokat
Bureau of Competition
Federal Trade Commission
Washington, D.C. 20004
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Christopher Curran
White & Case LLP
601 13th St., N.W.
Washington, D.C. 20005

Cathy Hoffman
Arnold & Porter
555 12th St., N.W.
Washington, D.C. 20004

David D. Chase

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

May 30, 2001

Via first class mail and facsimile

Michael N. Sohn, Esq.
Arnold & Porter
555 Twelfth Street, N.W.
Washington, D.C. 20004

Re: Schering-Plough Corp., Upsher-Smith Laboratories, ESI Lederle, Inc., Dkt. No. 9297

Dear Mr. Sohn:

Before we move forward with discovery in this matter, we felt it important to clear up some apparent confusion regarding the allegations in the Commission's complaint as they relate to ESI and the competitive harm caused by the Schering-ESI agreement. You seem to take the position (incorrectly) that the complaint does not allege ESI to be a potential competitor to Schering until March 2002, because the complaint correctly recognizes that Upsher-Smith is currently entitled to the Hatch-Waxman exclusivity period. Specifically, you stated at the prehearing conference on May 1, 2001:

> [F]rom the Commission's own complaint, Your Honor, ESI, whether or not it had settled with Schering. . . could not enter because of the operation of Hatch-Waxman, until March 2002.

This statement, however, is inconsistent with the complaint's theory of competitive harm resulting from the Schering-ESI agreement, and is fundamentally at odds with the state of law at the time this agreement was reached. Given this apparent misunderstanding, and to eliminate any conceivable future confusion, we have decided to provide you with the following summary of a theory of harm, which reflects – but also expands on – the allegations in the complaint.[1]

Under current law, Upsher – as the first generic applicant – is entitled to what is commonly referred to as a 180-day exclusivity period for generic K-Dur 20. This means that no other manufacturer of generic K-Dur 20 may obtain FDA approval to market its product until Upsher's

[1] Of course, nothing in this letter is intended to limit complaint counsel's ability to put forth any other theory of harm consistent with the allegations in the complaint.

180-day exclusivity period has expired. However, during the critical 7 months between the Schering/Upsher-Smith and Schering/ESI agreements, Upsher's eligibility for this right was in a state of legal flux and uncertainty.

- Under FDA's regulations existing in 1997, the first ANDA applicant submitting a paragraph IV certification (Upsher-Smith) had to successfully defend a patent infringement suit before it was eligible for the 180-day exclusivity right.

- This "successful defense" requirement, however, was under attack and had been challenged in the courts. In January 1997, a federal district court rejected the FDA's "successful defense" regulation, holding that the 180-day exclusivity period should be granted to the first ANDA applicant regardless of whether the applicant had successfully defended its patent infringement suit. *Mova Pharmaceuticals Corp. v. Shalala*, 955 F. Supp. 128 (D.D.C. 1997).

- In June 1997, Schering entered into its agreement with Upsher-Smith.

- Shortly thereafter, however, in July 1997, another federal district court upheld the FDA's successful defense regulation. *Granutec, Inc. v. Shalala*, No. 5:97-CV-485-BO (E.D.N.C. July 3, 1997).

- Schering then entered into an agreement in principle with ESI in January 1998 and dismissed its patent infringement litigation.

This legal and regulatory uncertainty in 1997 and early 1998 concerning Upsher's right to 180-day exclusivity under the Hatch-Waxman Act meant that both Upsher and ESI were potential competitive threats at the time of their respective agreements with Schering. Specifically, because of FDA's existing "successful defense" regulation, there was a possibility that Upsher would not become entitled to the exclusivity right until after it successfully defended its patent litigation with Schering. Therefore, under the FDA regulation in place in January 1998 when Schering and ESI reached a settlement in principle, ESI was a threat to enter before Upsher – and before March 2002 – if the courts upheld the FDA's "successful defense" regulations and ESI could receive final FDA approval. ESI's potential entry was a tangible threat that Schering successfully prevented.

We expect that the above explanation will clarify any confusion you had about how, according to the complaint, the Schering-ESI agreement delayed ESI's entry of a competitive generic K-Dur product. If you have any questions, please feel free to contact me.

Sincerely,

Karen S Bokat

Karen Bokat
Complaint Counsel

cc: Cathy Hoffman
Christopher Curran
Laura Shores